K041773

Section 21

JUL 15 2004

510(k) Summary

1. Date: 6th April 2004

2. Submitter/Manufacturer
City Technology Limited
City Technology Centre
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Portsmouth
Hampshire
PO6 1SZ
Great Britain

3. Contact Person
Debra Wallace
Quality/Environmental Systems Scientist

4. Contact
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5. Proprietary Device Name
MOX-1 Medical Oxygen Sensor
MOX-2 Medical Oxygen Sensor
MOX-3 Medical Oxygen Sensor
MOX-4 Medical Oxygen Sensor
MOX-5 Medical Oxygen Sensor
MOX-6 Medical Oxygen Sensor
MOX-7 Medical Oxygen Sensor
MOX-8 Medical Oxygen Sensor
MOX-9 Medical Oxygen Sensor
MOX-10 Medical Oxygen Sensor
MOX-16 Medical Oxygen Sensor

6. Classification Name
Oxygen Gas Analyzer (868.1720)

7. Common Name
Medical Oxygen Sensor

8. Predicate Devices
Ceramatec CAG-10 Sensor

9. Indications for Use

Purpose: The purpose of the City Technology Medical Oxygen sensors is to be the oxygen-sensing component to monitor the concentration of oxygen in breathing gas mixtures in finished medical devices at the point of manufacture. The additional purpose of the City Technology Medical Oxygen sensors is to be a replacement for the oxygen-sensing component after the life of the sensor originally supplied in the device is exhausted, to monitor the concentration of oxygen in breathing gas mixtures in medical devices.

Function: The City Technology Medical Oxygen sensors are used in medical device products such as Anaesthesia, Intensive Care and Incubators.

Target Patient Population: The target patient population consists of those patients who require the oxygen concentration in their breathing environment to be monitored.

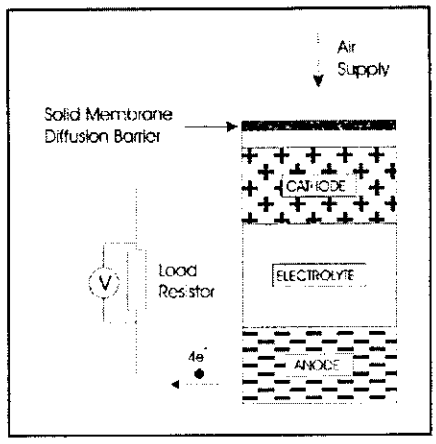
Environment of Use: The City Technology Medical Oxygen Sensors are used in medical devices (i.e. Anaesthesia, Intensive Care and Incubators) in patient environments whose temperatures range from -20°C to +50°C and from 0 to 99% humidity (non-condensing).

Device Claims: The City Technology Medical Oxygen Sensors consist of oxygen sensing components in medical devices that monitor the oxygen concentration in the patient's breathing environment.

Legally Marketed Predicate Device: The legally marketed predicate device is Ceramatec CAG-10 Oxygen Sensor. The predicate device was assigned 510(k) number K972992 and was declared substantially equivalent by FDA.

Safety and Effectiveness: No differences in intended use or application of the City Technology Medical Oxygen sensors or the predicate device have been identified that could affect safety or effectiveness.

10. Method of Operation:
These medical Oxygen sensors are based on the amperometric electrochemical measurement principle. The sensors comprise a plastic body in which are two electrodes, a precious metal cathode and a lead anode immersed in a liquid electrolyte solution, as in the schematic below.



Oxygen flows into the sensor through a solid membrane, which limits the flow and controls the output signal. Inside the sensor Oxygen reacts on the cathode to form hydroxyl ions as follows:

$$O_2 + 2H_2O + 4e^- \longrightarrow 4OH^-$$

These hydroxyl ions then oxidise the metal anode:

$$2Pb + 4OH^- \longrightarrow 2PbO + 2H_2O + 4e^-$$

Overall the effect is the consumption of the lead anode:

$$2Pb + O_2 \longrightarrow 2PbO$$

The electrons consumed at the cathode are supplied from the anode via the external circuit where a resistor is placed so that the voltage produced may be monitored. This voltage signal then constitutes a measure of the flux of Oxygen into the sensor and hence the partial pressure of Oxygen in front of the membrane.

The life of the sensor is governed by the mass of lead and the rate of consumption i.e. by the oxygen partial pressure; hence lifetimes are quoted as % Oxygen hours.

Accuracy is governed largely by the variation in diffusion rate of Oxygen through the solid membrane, which is a function of temperature and the presence of interfering gases that may absorb onto the membrane.

11. Intended Use

These sensors are designed to be used to monitor the partial pressure of oxygen in anaesthesia, critical care, incubators and general oxygen monitors.

12. Predicate Device Comparison

	Predicate Device CAG-10	CTL MOX-1, 2, 3, 4, 7, 8 & 10	CTL MOX-5, 6 and 9	CTL MOX-5	CTL MOX-16
Measurement Range	0-100%	0-1500 mBar	0-1500 mBar	0-1500 mBar	0-1500 mBar
T90	<15s	<15s	<15s	<20s	<15s
Operating Temperature Range	10-40°C	-20°C - +50°C	-20°C - +50°C	-20°C - +50°C	-20°C - +50°C
Operating Humidity Range	10-95% RH	0-99%RH	0-99% RH	0-99% RH	0-99% RH
Cross-Interference to Anaesthesia Agent Gases	<1%	<±2%	<±2%	<±2%	<±2%
Linearity	±2%	R^2>0.9999	R^2>0.9999	R^2>0.9999	R^2>0.9999
Operating Life	>900,000 $\%O_2$ Hours	1,600,000 % O_2 Hours	>900,000 $\%O_2$ Hours	>900,000 $\%O_2$ Hours	>650,000 $\%O_2$ Hours

The MOX-1, 2, 3, 4, 7, 8 and 10 Sensors differ only in body shape and electrical interface type, but are otherwise identical and can be considered equivalent.

The MOX-5, 6 and 9 Sensors differ only in body shape and electrical interface type, but are otherwise identical and can be considered equivalent.

The MOX-16 sensor is a dual cathode version of the other Medical Oxygen Sensors. It also has a different body shape and electrical interface, but otherwise it is identical and can therefore be considered equivalent.

13. Conclusion

City Technology's Medical Oxygen Sensors are substantially equivalent to the predicate devices listed. Medical Oxygen Sensors are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 5 2004

City Technology Limited
C/O Jeff D. Rongero
Underwriters Laboratories, Incorporated
12 Laboratory Drive
Research Triangle, NC 27709

Re: K041773
Trade/Device Name: Medical Oxygen Sensors, MOX -1, 2, 3, 4, 5, 6, 7, 8, 9, 10, and 16
Regulation Number: 868.1720
Regulation Name: Oxygen Gas Analyzer
Regulatory Class: II
Product Code: CCL
Dated: June 25, 2004
Received: July 1, 2004

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041773

Device Name: MOX-1,2,3,4,5,6,7,8,9,10 and 16
Medical Oxygen Sensors

Indications For Use: The City Technology Medical replacement oxygen sensor is intended to replace the original oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures.

Prescription Use__X___ OR Over-The-Counter Use_____
(Per 21CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041773

(Posted November 13, 2003)

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